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C. R. Bard, Inc. and
Bard Peripheral Vascular, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability MDL NO. 15-02641-PHX-DGC
Litigation

This Document Relates to:

LINDA SCHWESKA and DANIEL P.
SCHWESKA, her husband,

Plaintiffs,

Case No. CV-15-1879-PHX-DGC

v.

C. R. BARD, INC., a New Jersey
Corporation; AND BARD PERIPHERAL
VASCULAR INC., an Arizona
Corporation,

**DEFENDANTS C. R. BARD, INC. AND
BARD PERIPHERAL VASCULAR,
INC.'S ANSWER AND AFFIRMATIVE
DEFENSES AND DEMAND FOR
TRIAL BY JURY**

Defendants.

Defendants C. R. Bard, Inc. (“Bard”) and Bard Peripheral Vascular, Inc. (“BPV”) (Bard and BPV are collectively “Defendants”) answer the Complaint (“Plaintiffs’ Complaint”) of Plaintiffs Linda Schweska and Daniel P. Schweska (“Plaintiffs”) as follows:

PARTIES

1. To the extent the allegations in Paragraph 1 of Plaintiffs’ Complaint purport to cast liability upon Defendants, either directly or indirectly, those allegations are denied. Defendants are without information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. Defendants deny the remaining allegations contained in Paragraph 1 of Plaintiffs’ Complaint.

2. Defendants admit that Bard is a New Jersey Corporation and that Bard is authorized to do business, and does business, in the State of Illinois. Defendants admit that Bard owns a facility where vena cava filters are manufactured. Defendants deny any remaining allegations contained in Paragraph 2 of Plaintiffs’ Complaint.

3. Defendants admit that BPV is an Arizona Corporation and that BPV is authorized to do business, and does business, in the State of Illinois. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV has designed, sold, marketed, and distributed filters under the trademarks Recovery® and G2® Filter Systems. Defendants further admit that BPV is a wholly owned subsidiary of Bard. Defendants deny any remaining allegations contained in Paragraph 3 of Plaintiffs’ Complaint.

4. Paragraph 4 of Plaintiffs’ Complaint does not include any factual allegations and, as a result, requires no response by Defendants. However, to the extent Paragraph 4 purports to cast liability either directly or indirectly upon Defendants, said Paragraph is expressly denied.

5. The allegations of Paragraph 5 of Plaintiffs’ Complaint are not directed to Bard or BPV, and, as a result, require no response by Defendants. However, to the extent

1 Paragraph 5 purports to cast liability either directly or indirectly upon Defendants, said
2 Paragraph is expressly denied.

3 6. The allegations of Paragraph 6 of Plaintiffs' Complaint are not directed to Bard
4 or BPV, and, as a result, require no response by Defendants. However, to the extent
5 Paragraph 6 purports to cast liability either directly or indirectly upon Defendants, said
6 Paragraph is expressly denied.

7 **JURISDICTION AND VENUE**

8 7. Defendants do not dispute that, based on the facts as alleged by Plaintiff, which
9 have not been and could not have been confirmed by Defendants, jurisdiction appears to be
10 proper in this Court. However, Defendants deny that they are liable to Plaintiff for any
11 amount whatsoever and deny that Plaintiff has suffered any damages whatsoever.

12 8. Defendants do not dispute that, based on the facts as alleged by Plaintiff, which
13 have not been and could not have been confirmed by Defendants, jurisdiction appears to be
14 proper in the United States District Court for the Central District of Illinois. However,
15 Defendants deny that they are liable to Plaintiff for any amount whatsoever and deny that
16 Plaintiff has suffered any damages whatsoever.

17 9. Defendants do not dispute that, based on the facts as alleged by Plaintiff, which
18 have not been and could not have been confirmed by Defendants, venue appears to be proper
19 in the United States District Court for the Central District of Illinois.

20 **ALLEGATIONS**

21 10. Defendants deny the allegations contained in Paragraph 10 of Plaintiffs'
22 Complaint.

23 11. Defendants admit that Bard designed, manufactured, and sold a device named
24 the G2® Filter. Defendants admit that inferior vena cava filters are intended to prevent injury
25 or death resulting from venous thrombosis and pulmonary embolism. Defendants further
26 admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV
27 designed, sold, marketed, and distributed filters under the trademark G2® Filter System.
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1 Defendants deny any remaining allegations contained in Paragraph 11 of Plaintiffs'
2 Complaint.

3 12. Defendants deny the allegations contained in Paragraph 12 of Plaintiffs'
4 Complaint, including all sub-parts thereof.

5 13. Defendants lack knowledge or information sufficient to form a belief as to the
6 truth of the allegation regarding the time frame when inferior vena cava filters were first
7 introduced on the market or the identity of manufacturers of inferior vena cava filters.
8 Defendants deny any remaining allegations of Paragraph 13 of Plaintiffs' Complaint.

9 14. Defendants admit that inferior vena cava filters are intended to prevent injury or
10 death resulting from venous thrombosis and pulmonary embolism. Defendants further admit
11 that inferior vena cava filters may be designed for permanent placement, temporary
12 placement, or both. Defendants deny any remaining allegations of Paragraph 14 of Plaintiffs'
13 Complaint.

14 15. Defendants admit that the inferior vena cava is a large vein that receives blood
15 from the lower regions of the body and delivers it to the right atrium of the heart. Defendants
16 further admit that deep vein thrombosis and pulmonary emboli present dangerous risks to
17 human health, including sometimes death. Defendants deny any remaining allegations of
18 Paragraph 15 of Plaintiffs' Complaint.

19 16. Defendants admit that certain people are at an increased risk for the
20 development of deep vein thrombosis and pulmonary embolus, but lack sufficient information
21 to form a belief as to the truth of the allegations as stated regarding the various risk factors
22 which may predispose an individual to deep vein thrombosis or pulmonary emboli and thus
23 deny them. Defendants deny any remaining allegations of Paragraph 16 of Plaintiffs'
24 Complaint.

25 17. Defendants admit that patients at a high risk for developing deep vein
26 thrombosis and pulmonary embolism are frequently treated with anticoagulation therapy,
27 including but not limited to the medications listed in Paragraph 17 of Plaintiffs' Complaint.
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1 Defendants further admit that inferior vena cava filters may also be used to treat patients who
2 are at a high risk for developing deep vein thrombosis and pulmonary embolism. Defendants
3 lack knowledge or information sufficient to form a belief as to the truth of any remaining
4 allegations contained in Paragraph 17 of Plaintiffs' Complaint and, on that basis, deny them.

5 18. Defendants lack knowledge or information or information sufficient to form a
6 belief as to the truth of the allegation regarding the time frame when inferior vena cava filters
7 were first introduced on the market. Defendants also lack knowledge or information sufficient
8 to form a belief as to the truth of the allegation regarding the time frame when optional or
9 retrievable filters came to be marketed or the other allegations regarding optional or
10 retrievable filters marketed by other manufacturers. Defendants admit that the Recovery®
11 and G2® Filters were cleared by the FDA for optional use as retrievable inferior vena cava
12 filters. Defendants deny any remaining allegations contained in Paragraph 18 of Plaintiffs'
13 Complaint.

14 19. Defendants admit that the Recovery® Filter was cleared by the FDA for
15 permanent placement on November 27, 2002, pursuant to an application submitted under
16 Section 510(k) of the Food, Drug and Cosmetic Act. The allegations pertaining to the
17 requirements of Section 510(k) contained in Footnote 1 are legal conclusions of law to which
18 no answer is required. Defendants deny any remaining allegations contained in Paragraph 19
19 of Plaintiffs' Complaint, including any allegations contained in Footnote 1.

20 20. Defendants admit that the Recovery® Filter was cleared by the FDA for
21 retrievable placement on July 25, 2003, pursuant to an application submitted under
22 Section 510(k) of the Food, Drug and Cosmetic Act. Defendants deny any remaining
23 allegations contained in Paragraph 20 of Plaintiffs' Complaint.

24 21. Defendants deny the allegations contained in Paragraph 21 of Plaintiffs'
25 Complaint.

26 22. Defendants admit that the Recovery® Filter consists of twelve, shape-memory
27 Nitinol wires emanating from a central Nitinol sleeve. Defendants further admit that the
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1 twelve wires form two levels of filtration for emboli: the legs provide the lower level of
2 filtration, and the arms provide the upper level of filtration. Defendants deny any remaining
3 allegations contained in Paragraph 22 of Plaintiffs' Complaint.

4 23. Defendants admit that a nickel-titanium alloy named Nitinol is used in the
5 manufacture of the Recovery Filter and further admits that Nitinol contains shape memory.
6 However, to the extent Paragraph 23 purports to cast liability either directly or indirectly
7 upon Defendants, said Paragraph is expressly denied.

8 24. Defendants admit that the Recovery® Filter was designed to be inserted
9 endovascularly. Defendants further admit that the Recovery® Filter is designed to be
10 delivered via an introducer sheath, which is included in the delivery system for the device.
11 Defendants are without knowledge or information sufficient to form a belief as to the truth of
12 the allegations contained in Paragraph 24 of Plaintiffs' Complaint regarding the typical
13 practices of physicians, including physician methods for determining successful implantation
14 of the Recovery® Filter and, on that basis, such allegations are denied. Defendants deny any
15 remaining allegations of Paragraph 24 of Plaintiffs' Complaint.

16 25. Defendants deny the allegations contained in Paragraph 25 of Plaintiffs'
17 Complaint, including any allegations contained in Footnote 2.

18 26. Defendants deny the allegations contained in Paragraph 26 of Plaintiffs'
19 Complaint.

20 27. Defendants deny the allegations contained in Paragraph 27 of Plaintiffs'
21 Complaint.

22 28. Defendants admit that there are various well-documented complications that
23 may occur as a result of the fracture, perforation, and/or migration of any inferior vena cava
24 filter. Defendants further admit that it is well documented that many instances of filter
25 fracture, perforation, and and/or migration result in no complications whatsoever but, rather,
26 are completely asymptomatic. By way of further response, Bard states that there are incidents
27 related to the occurrence of known complications associated with every manufacturer of
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1 inferior vena cava filters. Defendants deny the remaining allegations of Paragraph 28 of
2 Plaintiffs' Complaint, including all sub-parts thereof.

3 29. Defendants deny the allegations contained in Paragraph 29 of Plaintiffs'
4 Complaint.

5 30. Defendants deny the allegations contained in Paragraph 30 of Plaintiffs'
6 Complaint.

7 31. Defendants deny the allegations contained in Paragraph 31 of Plaintiffs'
8 Complaint.

9 32. Defendants admit that there are various well-documented complications that
10 may occur as a result of the fracture, perforation, tilt and/or migration of any inferior vena
11 cava filter. Defendants further admit that it is well documented that many instances of filter
12 fracture, perforation, tilt, and/or migration result in no complications whatsoever but, rather,
13 are completely asymptomatic. By way of further response, Bard states that there are incidents
14 related to the occurrence of known complications associated with every manufacturer of
15 inferior vena cava filters. Defendants deny the remaining allegations of Paragraph 32 of
16 Plaintiffs' Complaint, including all sub-parts thereof.

17 33. Defendants deny the allegations contained in Paragraph 33 of Plaintiffs'
18 Complaint.

19 34. Defendants deny the allegations contained in Paragraph 34 of Plaintiffs'
20 Complaint.

21 35. Defendants admit that, as part of their continuing efforts to constantly evaluate
22 the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are
23 continually striving to improve the life-saving performance of those devices. The G2® Filter
24 was developed in furtherance of those efforts. Defendants deny the remaining allegations
25 contained in Paragraph 35 of Plaintiffs' Complaint.

26 36. Defendants admit the G2® Filter System was cleared by the United States Food
27 and Drug Administration pursuant to an application submitted under Section 510(k) of the
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1 Food, Drug and Cosmetic Act. Defendants admit that the G2® Filter was originally cleared
2 by the FDA for permanent use. Defendants further admit that the G2® Filter was
3 subsequently cleared by the FDA for optional use as a retrievable inferior vena cava filter.
4 Defendants deny any remaining allegations contained in Paragraph 36 of Plaintiffs'
5 Complaint.

6 37. Defendants admit that, as part of their continuing efforts to constantly evaluate
7 the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are
8 continually striving to improve the life-saving performance of those devices. The G2® Filter
9 was developed in furtherance of those efforts. Defendants deny any remaining allegations of
10 Paragraph 37 of Plaintiffs' Complaint.

11 38. Defendants deny the allegations contained in Paragraph 38 of Plaintiffs'
12 Complaint.

13 39. Defendants deny the allegations contained in Paragraph 39 of Plaintiffs'
14 Complaint.

15 40. Defendants admit that there are various well-documented complications that
16 may occur as a result of the fracture, perforation, tilt, and/or migration of any inferior vena
17 cava filter. Defendants further admit that it is well documented that many instances of filter
18 fracture, perforation, tilt, and/or migration result in no complications whatsoever but, rather,
19 are completely asymptomatic. By way of further response, Bard states that there are incidents
20 related to the occurrence of known complications associated with every manufacturer of
21 inferior vena cava filters. Defendants deny the remaining allegations of Paragraph 40 of
22 Plaintiffs' Complaint, including all sub-parts thereof.

23 41. Defendants admit that there are various well-documented complications that
24 may occur as the result of the fracture, perforation, tilt, and/or migration of any inferior vena
25 cava filter. Bard states that there are incidents related to the occurrence of known
26 complications associated with every manufacturer of inferior vena cava filters. By way of
27 further response, Bard states that information available in the public domain, including the
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1 FDA MAUDE database, is not a comprehensive analysis of all instances of such
2 complications. Defendants deny the remaining allegations of Paragraph 41 of Plaintiffs'
3 Complaint.

4 42. Defendants admit that there are various well-documented complications that
5 may occur as the result of the fracture, perforation, tilt, and/or migration of any inferior vena
6 cava filter. Bard states that there are incidents related to the occurrence of known
7 complications associated with every manufacturer of inferior vena cava filters. By way of
8 further response, Bard states that information available in the public domain, including the
9 FDA MAUDE database, is not a comprehensive analysis of all instances of such
10 complications. Defendants deny the remaining allegations of Paragraph 42 of Plaintiffs'
11 Complaint.

12 43. Defendants deny the allegations contained in Paragraph 43 of Plaintiffs'
13 Complaint.

14 44. Defendants deny the allegations contained in Paragraph 44 of Plaintiffs'
15 Complaint.

16 45. Defendants deny the allegations contained in Paragraph 45 of Plaintiffs'
17 Complaint.

18 46. Defendants deny the allegations contained in Paragraph 46 of Plaintiffs'
19 Complaint, including all-subparts thereof.

20 47. Defendants deny the allegations contained in Paragraph 47 of Plaintiffs'
21 Complaint.

22 48. Defendants deny the allegations contained in Paragraph 48 of Plaintiffs'
23 Complaint.

24 49. Defendants are without knowledge or information sufficient to form a belief as
25 to the truth of the allegations regarding the trade name of any inferior vena cava filter
26 implanted in Plaintiff and, on that basis, deny them. Defendants deny any remaining
27 allegations of Paragraph 49 of Plaintiffs' Complaint.
28

1 50. Defendants are without knowledge or information sufficient to form a belief as
2 to the truth of the allegations regarding the trade name of any inferior vena cava filter
3 implanted in Plaintiff and, on that basis, deny them. By way of further response, Defendants
4 admit that Bard owns a facility where vena cava filters are manufactured and that filters under
5 the trademark G2® Filter System were manufactured at that facility. Defendants further
6 admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV
7 designed, sold, marketed, and distributed filters under the trademark G2® Filter System.
8 Defendants deny any remaining allegations of Paragraph 50 of Plaintiffs' Complaint.

9 51. Defendants deny the allegations contained in Paragraph 51 of Plaintiffs'
10 Complaint.

11 52. Defendants deny the allegations contained in Paragraph 52 of Plaintiffs'
12 Complaint.

13 53. Defendants deny the allegations contained in Paragraph 53 of Plaintiffs'
14 Complaint.

15 54. Defendants deny the allegations contained in Paragraph 54 of Plaintiffs'
16 Complaint.

17 55. Defendants deny the allegations contained in Paragraph 55 of Plaintiffs'
18 Complaint.

19 56. Defendants deny the allegations contained in Paragraph 56 of Plaintiffs'
20 Complaint.

21 57. Defendants deny the allegations contained in Paragraph 57 of Plaintiffs'
22 Complaint.

23 58. Defendants deny the allegations contained in Paragraph 58 of Plaintiffs'
24 Complaint.

25 59. Defendants deny the allegations contained in Paragraph 59 of Plaintiffs'
26 Complaint.

FIRST CAUSE OF ACTION**NEGLIGENCE**

60. Defendants incorporate by reference their responses to Paragraphs 1-59 of Plaintiffs' Complaint as if fully set forth herein.

61. Defendants deny the allegations contained in Paragraph 61 of Plaintiffs' Complaint as stated. By way of further response, Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademarks Recovery® and G2® Filter Systems were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademarks Recovery® and G2® Filter Systems. Defendants deny any remaining allegations contained in Paragraph 61 of Plaintiffs' Complaint.

62. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. Defendants deny any remaining allegations of Paragraph 62 of Plaintiffs' Complaint.

63. The allegations contained in Paragraph 63 regarding Defendants' duty are legal conclusions of law, and no answer is required. To the extent a response is required, Defendants deny the allegations. Defendants deny the remaining allegations contained in Paragraph 63 of Plaintiffs' Complaint.

64. Defendants deny the allegations contained in Paragraph 64 of Plaintiffs' Complaint.

65. Defendants deny the allegations contained in Paragraph 65 of Plaintiffs' Complaint, including all sub-parts thereof.

66. Defendants deny the allegations contained in Paragraph 66 of Plaintiffs' Complaint.

67. Defendants deny the allegations contained in Paragraph 67 of Plaintiffs' Complaint.

68. Defendants deny the allegations contained in Paragraph 68 of Plaintiffs' Complaint, including all sub-parts thereof.

69. Defendants deny the allegations contained in Paragraph 69 of Plaintiffs' Complaint.

70. Defendants deny the allegations contained in Paragraph 70 of Plaintiffs' Complaint.

SECOND CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – FAILURE TO WARN

71. Defendants incorporate by reference their responses to Paragraphs 1-70 of Plaintiffs' Complaint as if fully set forth herein.

72. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. By way of further response, Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademark G2® Filter System were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademark G2® Filter System. Defendants deny any remaining allegations contained in Paragraph 72 of Plaintiffs' Complaint.

73. Defendants deny the allegations contained in Paragraph 73 of Plaintiffs' Complaint.

74. The allegations contained in Paragraph 74 regarding Defendants' duty are legal conclusions of law, and no answer is required. To the extent a response is required, Defendants deny the allegations. Defendants deny the remaining allegations contained in Paragraph 74 of Plaintiffs' Complaint.

75. Defendants deny the allegations contained in Paragraph 75 of Plaintiffs' Complaint.

76. Defendants deny the allegations contained in Paragraph 76 of Plaintiffs' Complaint.

77. Defendants deny the allegations contained in Paragraph 77 of Plaintiffs' Complaint.

78. Defendants deny the allegations contained in Paragraph 78 of Plaintiffs' Complaint.

79. Defendants deny the allegations contained in Paragraph 79 of Plaintiffs' Complaint.

80. Defendants deny the allegations contained in Paragraph 80 of Plaintiffs' Complaint.

81. Defendants deny the allegations contained in Paragraph 81 of Plaintiffs' Complaint.

THIRD CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – DESIGN DEFECTS

82. Defendants incorporate by reference their responses to Paragraphs 1-81 of Plaintiffs' Complaint as if fully set forth herein.

83. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. By way of further response, Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademark G2® Filter System were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademark G2® Filter System. Defendants deny any remaining allegations contained in Paragraph 83 of Plaintiffs' Complaint.

84. Defendants deny the allegations contained in Paragraph 84 of Plaintiffs' Complaint.

85. Defendants deny the allegations contained in Paragraph 85 of Plaintiffs' Complaint.

86. Defendants deny the allegations contained in Paragraph 86 of Plaintiffs' Complaint.

87. Defendants deny the allegations contained in Paragraph 87 of Plaintiffs' Complaint.

88. Defendants deny the allegations contained in Paragraph 88 of Plaintiffs' Complaint.

89. Defendants deny the allegations contained in Paragraph 89 of Plaintiffs' Complaint.

FOURTH CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

90. Defendants incorporate by reference their responses to Paragraphs 1-89 of Plaintiffs' Complaint as if fully set forth herein.

91. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. By way of further response, Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademark G2® Filter System were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademark G2® Filter System. Defendants deny any remaining allegations contained in Paragraph 91 of Plaintiffs' Complaint.

92. Defendants deny the allegations contained in Paragraph 92 of Plaintiffs' Complaint.

103. Defendants deny the allegations contained in Paragraph 103 of Plaintiffs' Complaint.

104. Defendants deny the allegations contained in Paragraph 104 of Plaintiffs' Complaint.

105. Defendants deny the allegations contained in Paragraph 105 of Plaintiffs' Complaint.

SIXTH CAUSE OF ACTION

NEGLIGENT MISREPRESENTATION/CONSUMER FRAUD

106. Defendants incorporate by reference their responses to Paragraphs 1-105 of Plaintiffs' Complaint as if fully set forth herein.

107. Defendants deny the allegations contained in Paragraph 107 of Plaintiffs' Complaint, including all subparts thereof.

108. Defendants deny the allegations contained in Paragraph 108 of Plaintiffs' Complaint.

109. Defendants deny the allegations contained in Paragraph 109 of Plaintiffs' Complaint.

110. Defendants deny the allegations contained in Paragraph 110 of Plaintiffs' Complaint.

111. Defendants deny the allegations contained in Paragraph 111 of Plaintiffs' Complaint.

112. Defendants deny the allegations contained in Paragraph 112 of Plaintiffs' Complaint.

113. Defendants deny the allegations contained in Paragraph 113 of Plaintiffs' Complaint.

114. Defendants deny the allegations contained in Paragraph 114 of Plaintiffs' Complaint.

1 115. Defendants deny the allegations contained in Paragraph 115 of Plaintiffs'
2 Complaint.

3 116. Defendants deny the allegations contained in Paragraph 116 of Plaintiffs'
4 Complaint.

5 **SEVENTH CAUSE OF ACTION**

6 **LOSS OF CONSORTIUM**

7 117. Defendants incorporate by reference their responses to Paragraphs 1-116 of
8 Plaintiffs' Complaint as if fully set forth herein.

9 118. Defendants are without information or knowledge sufficient to form a belief as
10 to the truth of the allegations contained in Paragraph 118 of Plaintiffs' Complaint and,
11 therefore, deny them.

12 119. Defendants deny the allegations contained in Paragraph 119 of Plaintiffs'
13 Complaint.

14 120. Defendants deny the allegations contained in Paragraph 120 of Plaintiffs'
15 Complaint.

16 121. Defendants deny the allegations contained in Paragraph 121 of Plaintiffs'
17 Complaint.

18 122. Defendants deny the allegations contained in Paragraph 122 of Plaintiffs'
19 Complaint.

20 **PUNITIVE DAMAGES ALLEGATIONS**

21 123. Defendants incorporate by reference their responses to Paragraphs 1-122 of
22 Plaintiffs' Complaint as if fully set forth herein.

23 124. Defendants deny the allegations contained in Paragraph 124 of Plaintiffs'
24 Complaint.

25 125. Defendants deny the allegations contained in Paragraph 125 of Plaintiffs'
26 Complaint, including all sub-parts thereof.

1 126. Defendants deny the allegations contained in Paragraph 126 of Plaintiffs'
2 Complaint.

3 127. Defendants deny the allegations contained in Paragraph 127 of Plaintiffs'
4 Complaint.

5 **PRAYER FOR DAMAGES**

6 Furthermore, responding to the unnumbered Paragraph, including sub-parts, following
7 the heading "PRAYER FOR DAMAGES" and beginning "WHEREFORE," Defendants deny
8 the allegations contained in such Paragraph and sub-parts.

9 Further, responding to the unnumbered Paragraph regarding Plaintiffs' allegations of
10 negligence, Defendants deny the allegations contained in such Paragraph, including all
11 subparts thereof. Defendants deny that Plaintiffs are entitled to any relief requested in the
12 Plaintiffs' Complaint.

13 Further, responding to the unnumbered Paragraph regarding Plaintiffs' allegations of
14 strict liability failure to warn, Defendants deny the allegations contained in such Paragraph,
15 including all subparts thereof. Defendants deny that Plaintiffs are entitled to any relief
16 requested in the Plaintiffs' Complaint.

17 Further, responding to the unnumbered Paragraph regarding Plaintiffs' allegations of
18 strict liability design defect, Defendants deny the allegations contained in such Paragraph,
19 including all subparts thereof. Defendants deny that Plaintiffs are entitled to any relief
20 requested in the Plaintiffs' Complaint.

21 Further, responding to the unnumbered Paragraph regarding Plaintiffs' allegations of
22 strict liability manufacturing defect, Defendants deny the allegations contained in such
23 Paragraph, including all subparts thereof. Defendants deny that Plaintiffs are entitled to any
24 relief requested in the Plaintiffs' Complaint.

25 Further, responding to the unnumbered Paragraph regarding Plaintiffs' allegations of
26 breach of implied warranty, Defendants deny the allegations contained in such Paragraph,
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1 including all subparts thereof. Defendants deny that Plaintiffs are entitled to any relief
2 requested in the Plaintiffs' Complaint.

3 Further, responding to the unnumbered Paragraph regarding Plaintiffs' allegations of
4 negligent misrepresentation/consumer fraud, Defendants deny the allegations contained in
5 such Paragraph, including all subparts thereof. Defendants deny that Plaintiffs are entitled to
6 any relief requested in the Plaintiffs' Complaint.

7 Further, responding to the unnumbered Paragraph regarding Plaintiffs' allegations of
8 loss of consortium, Defendants deny the allegations contained in such Paragraph, including
9 all subparts thereof. Defendants deny that Plaintiffs are entitled to any relief requested in the
10 Plaintiffs' Complaint.

11 Defendants further deny each and every allegation not specifically admitted herein.

12 **DEFENSES**

13 Defendants allege as affirmative defenses the following:

14 1. Plaintiffs' Complaint fails to state a claim or claims upon which relief can be
15 granted under Rule 12 of the Federal Rules of Civil Procedure.

16 2. The sole proximate cause of Plaintiffs' damages, if any were sustained, was the
17 negligence of a person or persons or entity for whose acts or omissions Defendants were and
18 are in no way liable.

19 3. Plaintiffs' claims are barred, in whole or in part, by the applicable statutes of
20 limitations and/or statute of repose.

21 4. If Plaintiffs have been damaged, which Defendants deny, any recovery by
22 Plaintiffs is barred to the extent Plaintiffs voluntarily exposed themselves to a known risk
23 and/or failed to mitigate their alleged damages. To the extent Plaintiffs have failed to mitigate
24 their alleged damages, any recovery shall not include alleged damages that could have been
25 avoided by reasonable care and diligence.

26 5. If Plaintiffs have been damaged, which Defendants deny, such damages were
27 caused by the negligence or fault of Plaintiffs.

1 6. If Plaintiffs have been damaged, which Defendants deny, such damages were
2 caused by the negligence or fault of persons and/or entities for whose conduct Defendants are
3 not legally responsible.

4 7. The conduct of Defendants and the subject product at all times conformed with
5 the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301, *et seq.*, and other pertinent
6 federal statutes and regulations. Accordingly, Plaintiffs' claims are barred, in whole or in
7 part, under the doctrine of federal preemption, and granting the relief requested would
8 impermissibly infringe upon and conflict with federal laws, regulations, and policies in
9 violation of the Supremacy Clause of the United States Constitution.

10 8. If Plaintiffs have been damaged, which Defendants deny, such damages were
11 caused by unforeseeable, independent, intervening, and/or superseding events for which
12 Defendants are not legally responsible.

13 9. There was no defect in the product at issue with the result that Plaintiffs are not
14 entitled to recover against Defendants in this cause.

15 10. If there were any defect in the products – and Defendants deny that there were
16 any defects – nevertheless, there was no causal connection between any alleged defect and
17 the product on the one hand and any damage to Plaintiffs on the other with the result that
18 Plaintiffs are not entitled to recover against Defendants in this cause.

19 11. Plaintiffs' injuries, losses or damages, if any, were caused by or contributed to
20 by other persons or entities that are severally liable for all or part of Plaintiffs' alleged
21 injuries, losses or damages. If Defendants are held liable to Plaintiffs, which liability is
22 specifically denied, Defendants are entitled to contribution, set-off, and/or indemnification,
23 either in whole or in part, from all persons or entities whose negligence or fault proximately
24 caused or contributed to cause Plaintiffs' alleged damages.

25 12. Plaintiffs' claims are barred to the extent that the injuries alleged in the
26 Plaintiffs' Complaint were caused by the abuse, misuse, abnormal use, or use of the product
27 at issue in a manner not intended by Defendants and over which Defendants had no control.
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1 13. Plaintiffs' claims are barred to the extent that the injuries alleged in the
2 Plaintiffs' Complaint were caused by a substantial change in the product after leaving the
3 possession, custody, and control of Defendants.

4 14. Plaintiffs' breach of warranty claims are barred because: (1) Defendants did not
5 make any warranties, express or implied, to Plaintiffs; (2) there was a lack of privity between
6 Defendants and Plaintiffs; and (3) notice of an alleged breach was not given to the seller or
7 Defendants.

8 15. Plaintiffs' claims for breach of implied warranty must fail because the product
9 was not used for its ordinary purpose.

10 16. Defendants neither had nor breached any alleged duty to warn with respect to
11 the product, with the result that Plaintiffs are not entitled to recover in this cause.

12 17. Plaintiffs' claims are barred by Defendants' dissemination of legally adequate
13 warnings and instructions to learned intermediaries.

14 18. At all relevant times, herein, Plaintiffs' physicians were in the position of
15 sophisticated purchasers, fully knowledgeable and informed with respect to the risks and
16 benefits of the subject product.

17 19. If Plaintiffs have been damaged, which Defendants deny, the actions of persons
18 or entities for whose conduct Defendants are not legally responsible and the independent
19 knowledge of these persons or entities of the risks inherent in the use of the product and other
20 independent causes, constitute an intervening and superseding cause of Plaintiffs' alleged
21 damages.

22 20. To the extent that injuries and damages sustained by Plaintiffs, as alleged in
23 Plaintiffs' Complaint, were caused directly, solely, and proximately by sensitivities, medical
24 conditions, and idiosyncrasies peculiar to Plaintiffs not found in the general public, they were
25 unknown, unknowable, or not reasonably foreseeable to Defendants.

26 21. Defendants believe, and upon that ground allege, that Plaintiffs were advised of
27 the risks associated with the matters alleged in Plaintiffs' Complaint and knowingly and
28

1 voluntarily assumed them. Pursuant to the doctrine of assumption of the risk, informed
2 consent, release, waiver, or comparative fault, this conduct bars in whole or in part the
3 damages that Plaintiffs seek to recover herein.

4 22. At all relevant times during which the device at issue was designed, developed,
5 manufactured, and sold, the device was reasonably safe and reasonably fit for its intended
6 use, was not defective or unreasonably dangerous, and was accompanied by proper warnings,
7 information, and instructions, all pursuant to generally recognized prevailing industry
8 standards and state-of-the-art in existence at the time.

9 23. Plaintiffs' claims are barred because Plaintiffs suffered no injury or damages as
10 a result of the alleged conduct and do not have any right, standing, or competency to maintain
11 claims for damages or other relief.

12 24. Plaintiffs' claims are barred, in whole or in part, by the doctrines of waiver,
13 estoppel, and/or laches.

14 25. If Plaintiffs suffered any damages or injuries, which is denied, Defendants state
15 that Plaintiffs' recovery is barred, in whole or in part, or subject to reduction, under the
16 doctrines of contributory and/or comparative negligence.

17 26. In the further alternative, and only in the event that it is determined that
18 Plaintiffs are entitled to recover against Defendants, recovery should be reduced in proportion
19 to the degree or percentage of negligence, fault or exposure to products attributable to
20 Plaintiffs, any other defendants, third-party defendants, or other persons, including any party
21 immune because bankruptcy renders them immune from further litigation, as well as any
22 party, co-defendant, or non-parties with whom Plaintiffs have settled or may settle in the
23 future.

24 27. Should Defendants be held liable to Plaintiffs, which liability is specifically
25 denied, Defendants would be entitled to a setoff for the total of all amounts paid to Plaintiffs
26 from all collateral sources.

1 28. Plaintiffs' claims may be barred, in whole or in part, from seeking recovery
2 against Defendants pursuant to the doctrines of *res judicata*, collateral estoppel, release of
3 claims, and the prohibition on double recovery for the same injury.

4 29. The injuries and damages allegedly sustained by Plaintiffs may be due to the
5 operation of nature or idiosyncratic reaction(s) and/or pre-existing condition(s) in Plaintiffs
6 over which Defendants had no control.

7 30. The conduct of Defendants and all activities with respect to the subject product
8 have been and are under the supervision of the Federal Food and Drug Administration
9 ("FDA"). Accordingly, this action, including any claims for monetary and/or injunctive relief,
10 is barred by the doctrine of primary jurisdiction and exhaustion of administrative remedies.

11 31. Defendants assert any and all defenses, claims, credits, offsets, or remedies
12 provided by the Restatements (Second and Third) of Torts and reserve the right to amend
13 their Answer to file such further pleadings as are necessary to preserve and assert such
14 defenses, claims, credits, offsets, or remedies.

15 32. The device at issue complied with any applicable product safety statute or
16 administrative regulation, and therefore Plaintiffs' defective design and warnings-based
17 claims are barred under the Restatement (Third) of Torts: Products Liability § 4, *et seq.* and
18 comments thereto.

19 33. Plaintiffs cannot show that any reasonable alternative design would have
20 rendered the Eclipse™ Filter to be safer overall under the Restatement (Third) of Product
21 Liability § 2, cmt. f, nor could Defendants have known of any alternative design that may be
22 identified by Plaintiff.

23 34. The device at issue was not sold in a defective condition unreasonably
24 dangerous to the user or consumer, and therefore Plaintiffs' claims are barred under the
25 Restatement (Second) of Torts: Products Liability § 402A and comments thereto, and
26 comparable provisions of the Restatement (Third) of Torts (Products Liability).

1 35. At all relevant times during which the device at issue was designed, developed,
2 manufactured, and sold, the device was reasonably safe and reasonably fit for its intended
3 use, was not defective or unreasonably dangerous, and was accompanied by proper warnings,
4 information, and instructions, all pursuant to generally recognized prevailing industry
5 standards and state-of-the-art in existence at the time.

6 36. Defendants specifically plead all affirmative defenses under the Uniform
7 Commercial Code (“UCC”) now existing or which may arise in the future, including those
8 defenses provided by UCC §§ 2-607 and 2-709.

9 37. Plaintiffs’ alleged damages, if any, should be apportioned among all parties at
10 fault, and any non-parties at fault.

11 38. No act or omission of Defendants was malicious, willful, wanton, reckless, or
12 grossly negligent, and, therefore, any award of punitive damages is barred.

13 39. To the extent the claims asserted in Plaintiffs’ Complaint are based on a theory
14 providing for liability without proof of defect and proof of causation, the claims violate
15 Defendants’ rights under the Constitution of the United States and analogous provisions of
16 the Illinois Constitution.

17 40. Regarding Plaintiffs’ demand for punitive damages, Defendants specifically
18 incorporate by reference any and all standards of limitations regarding the determination
19 and/or enforceability of punitive damages awards that arose in the decisions of *BMW of*
20 *No. America v. Gore*, 517 U.S. 559 (1996); *Cooper Industries, Inc. v. Leatherman Tool*
21 *Group, Inc.*, 532 U.S. 424 (2001); *State Farm Mut. Auto Ins. Co. v. Campbell*, 123 S. Ct.
22 1513 (2003); and *Exxon Shipping Co. v. Baker*, No. 07-219, 2008 U.S. LEXIS 5263 (U.S.
23 June 25, 2008) and their progeny as well as other similar cases under both federal and state
24 law.

25 41. Plaintiffs’ claims for punitive or exemplary damages violate, and are therefore
26 barred by, the Fourth, Fifth, Sixth, Eighth and Fourteenth Amendments to the Constitution of
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1 the United States of America, and similar provisions of the Illinois Constitution, on grounds
2 including the following:

- 3 (a) it is a violation of the Due Process and Equal Protection Clauses of the
4 Fourteenth Amendment of the United States Constitution to impose punitive
5 damages, which are penal in nature, against a civil defendant upon the plaintiffs
6 satisfying a burden of proof which is less than the “beyond a reasonable doubt”
7 burden of proof required in criminal cases;
- 8 (b) the procedures pursuant to which punitive damages are awarded may result in
9 the award of joint and several judgments against multiple defendants for
10 different alleged acts of wrongdoing, which infringes upon the Due Process and
11 Equal Protection Clauses of the Fourteenth Amendment of the United States
12 Constitution;
- 13 (c) the procedures to which punitive damages are awarded fail to provide a
14 reasonable limit on the amount of the award against Defendants, which thereby
15 violates the Due Process Clause of the Fourteenth Amendment of the United
16 States Constitution;
- 17 (d) the procedures pursuant to which punitive damages are awarded fail to provide
18 specific standards for the amount of the award of punitive damages which
19 thereby violates the Due Process Clause of the Fourteenth Amendment of the
20 United States Constitution;
- 21 (e) the procedures pursuant to which punitive damages are awarded result in the
22 imposition of different penalties for the same or similar acts, and thus violate
23 the Equal Protection Clause of the Fourteenth Amendment of the United States
24 Constitution;
- 25 (f) the procedures pursuant to which punitive damages are awarded permit the
26 imposition of punitive damages in excess of the maximum criminal fine for the
27 same or similar conduct, which thereby infringes upon the Due Process Clause
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of the Fifth and Fourteenth Amendments and the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution;

(g) the procedures pursuant to which punitive damages are awarded permit the imposition of excessive fines in violation of the Eighth Amendment of the United States Constitution;

(h) the award of punitive damages to the plaintiff in this action would constitute a deprivation of property without due process of law; and

(i) the procedures pursuant to which punitive damages are awarded permit the imposition of an excessive fine and penalty.

42. Defendants expressly reserve the right to raise as an affirmative defense that Plaintiffs have failed to join all parties necessary for a just adjudication of this action, should discovery reveal the existence of facts to support such defense.

43. Defendants reserve the right to raise such other affirmative defenses as may be available or apparent during discovery or as may be raised or asserted by other defendants in this case. Defendants have not knowingly or intentionally waived any applicable affirmative defense. If it appears that any affirmative defense is or may be applicable after Defendants have had the opportunity to conduct reasonable discovery in this matter, Defendants will assert such affirmative defense in accordance with the Federal Rules of Civil Procedure.

REQUEST FOR JURY TRIAL

Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. demand a trial by jury on all issues appropriate for jury determination.

WHEREFORE, Defendants aver that Plaintiff is not entitled to the relief demanded in the Plaintiffs' Complaint, and these Defendants, having fully answered, pray that this action against them be dismissed and that they be awarded their costs in defending this action and that they be granted such other and further relief as the Court deems just and appropriate.

1 This 27th day of October, 2015.

2
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23 **Bard Peripheral Vascular, Inc.**
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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on October 27, 2015, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send notification of such filing to all counsel of record.

s/Richard B. North, Jr.
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